12/10/99

K 993103

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353 Corporate Woods Parkway
Vernon Hills, Illinois 60061
Phone: 847.913.1113
Fax: 847.913.1488

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			**FDA establishment registration number:** 14 184 79
Division name (if applicable): N.A.			**Phone number (include area code):** (847) 913-1113
Street address: 353 Corporate Woods Parkway			**FAX number (include area code):** (847) 913-0924
City: Vernon Hills	**State/Province:** Illinois	**Country:** USA	**ZIP / Postal Code:** 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Trade name: Endoscope	**Model number:** 8934.431, 8934.432, 8934.433
Common name: Endoscope	**Classification name:** Endoscope

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enact.	1 endoscope lumina 8934.40	1 Richard Wolf
2 K980129 / K972927	2 endoscope, Panoview Plus	2 Richard Wolf
3	3 OES telescopes A5216/A5205	3 Olympus
4	4 Hopkins telescopes 26033 AP/BP	4 Storz

1.0 Description

The submitted endoscopes are standard laparoscopes without operation channel with improved aging durability.

2.0 Intended Use

The endoscopes serve to visualize the inside of the patient via natural or surgically generated access.

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3.0 Technological Characteristics

Improved aging durability is achieved by: 1) soldering the cover glass to the jacket sheath, 2) using gas-tight sealings and steam-tight sealings, and 3) by using stainless steel for all metal parts. The optical specification, the dimensions and the interfaces are maintained.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing) devices sold by Richard Wolf.

5.0 Performance Data

No performance standards are known.

The devices conform to international standards IEC-601-, IEC 601-2-18, and to the relevant provisions of European Device Directive 93/42/EEC.

6.0 Clinical Tests

Clinical tests performed were not performed.

7.0 Conclusions Drawn

These devices are designed and tested to assure their safety and effectiveness when used according to the instructions manual.

By: Robert L. Casarsa Date: Sept 13, 1999

Robert L. Casarsa
Quality Assurance Manager

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1999

Mr. Robert L. Casarsa
Quality Assurance Manager
RICHARD WOLF
Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K993103
Rigid Endoscopes, 10mm diameter, Models 8934.431, 0°; 8934.432, 30°; and 8934.433, 50°
Dated: September 10, 1999
Received: September 16, 1999
Regulatory Class: II
21 CFR 876.1500/Procode: 78 KOG, GCM, and GCJ

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K993103

Device Name: Endoscopes

Intended Use:

The endoscopes serve to visualize the inside of the patient via natural or surgically generated access.

Indications and Application:

For examination, diagnosis, and / or therapy by personnel trained and qualified in connection with endoscopically used accessories in various medical disciplines, such as surgery, urology, gynecology, and ENT.

Contraindications:

Contraindications directly related to the product are currently unknown.

The attending physician must determine if the intended application is appropriate based on the general condition of the patient.

For further instructions, please refer to the current technical literature.

Combinations:

The endoscopes are used in connection with light sources and flexible light cables, video cameras, or reflex cameras and objective lenses, as well as accessories for endoscopic use, e.g. trocar sleeves, forceps, electrodes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993103

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Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter